Laboratory Certification Standards Review Council Meeting Minutes From 11/09/2010

Attendance

Council Members: Dave Kliber (Chair), Sue Hill (Vice-Chair), Randy Thater, Kirsti Sorsa, Chris Groh [via LiveMeeting], Steve Jossart [via LiveMeeting],.
Absent: Judy Tholen

DNR Staff: Jack Sullivan (Bureau Director, Science Services), Kelly Thompson (Interim Chief, Lab Certification), Rick Mealy

Others in Attendance: Paul Harris (Davy Labs), Paul Junio (Northern Lake Service), Sharon Mertens (Milwaukee MSD)

Others Via LiveMeeting: Tom Priebe (Northern Lake Service), Tom Hungerford (S-F Analytical)

Summary and Action Items

At this meeting the Certification Standards Review Council:

- o approved minutes of its August 10 meeting,
- o reviewed program audit performance,
- o agreed to revisit the impacts of the Phosphorus rule at its February meeting,
- o suggested that the program's SOP for on-site evaluations be reviewed at its February meeting,
- o tentatively scheduled the Council's next meeting for Tuesday, February 8, 2011.

Agenda Items

I. Check in/Agenda Repair

A. Jack Sullivan asked for time to update the council on the section chief vacancy.

II, Review and Approval of Draft Minutes from August 10, 2010 Meeting

A. A motion *(Hill/Thater)* to approve the minutes with correction of a number of minor changes discussed during the meeting was approved.

III. Program Performance Status Report- for FY11 Year-to-Date

A. Council members were presented with program audit statistics for the current fiscal 2011, as well as backlog information as summarized in the figures below.

B. Program-wide, compliance with the 30 day turnaround time for audit reports to be issued is at 51 % for fiscal 2011 (21 of 41 reports issued). For the commercial/public health lab sector, compliance is at 18% (2 of 11 reports issued within 30 days). For the municipal/industrial sector, the compliance rate is 67% (20 of 30 reports).

FY2011 Cumulative Totals

	CENTRAL OFFICE			REGIONAL		
	Total YTD	Goals		Total YTD	Goals	(*Goals based on audit every 3 years*)
Audits	4	35		34	97	
Reports	11	35		30	97	
Closures	9	35		20	97	
Reports Due	8			9		
Open Cases	23			65		

FY2011 Quarterly Totals

1st Quarter	2nd Quarter	3rd Quarter	4th Quarter

CENTRAL OFFICE

Audits	**3**	*1*		
Reports	**8**	*3*		
Closures	**6**	*3*		

	AUG	NOV	FEB	MAY
Pending Reports	13	8		
Open Cases	28	23		

REGIONAL

Audits	**27**	*7*		
Reports	**17**	*13*		
Closures	**15**	*5*		

Pending Reports	12	9		
Open Cases	58	65		

Total Labs by Responsibility	Nov '10	May '08	Nov '07	May '07	Oct '06	May '06
Commercial/Pubic Health	103	110	113	121	122	123
Municipal/Industrial	285	302	301	302	298	302
Total Audit Responsibility	**388**	**412**	**414**	**423**	**420**	**425**
Reciprocity	8	7	7	8	8	11

Audit Report Turnaround Time FY 2011 only
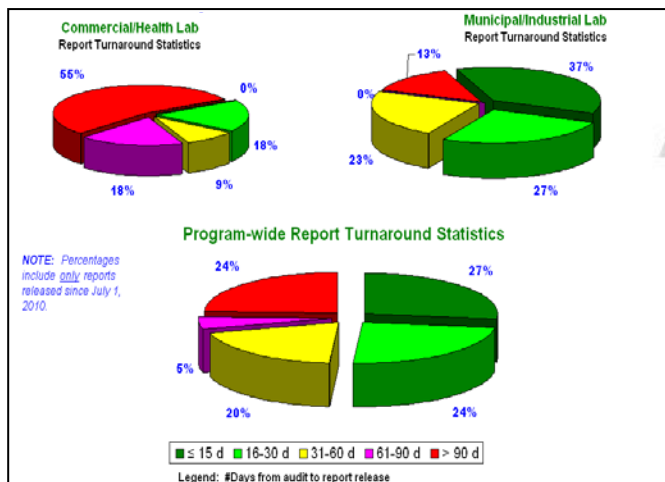
Audit Report Turnaround Time since 9/1/08

PENDING AUDIT REPORTS

30 days ≈ 3 reports

30 days ≈ 8 reports

OPEN CASES

50% of goal ≈ 17 open cases
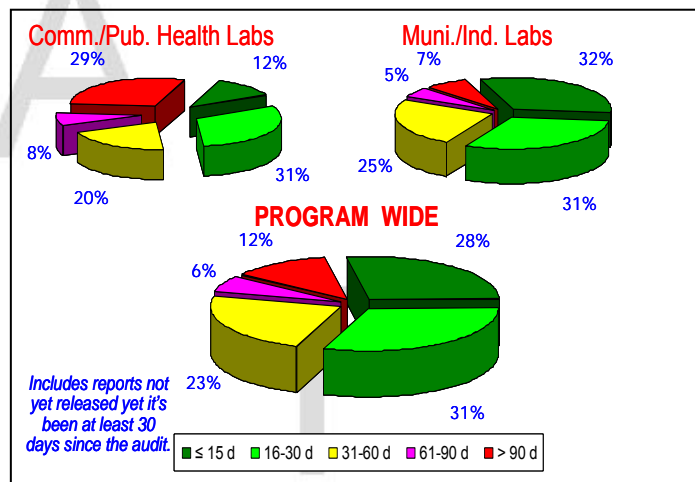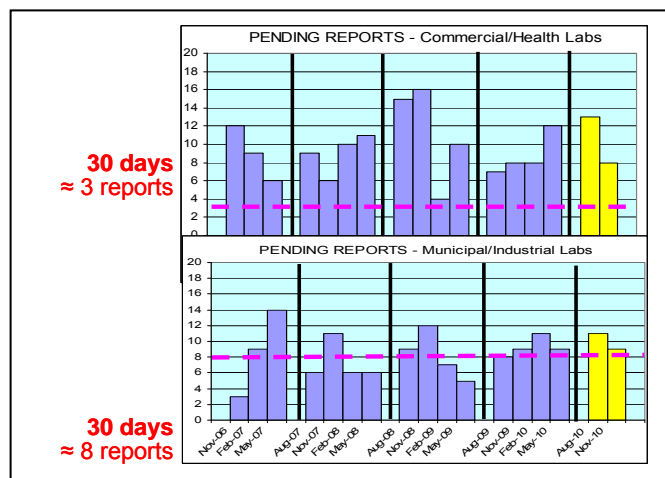
50% of goal ≈ 48 open cases
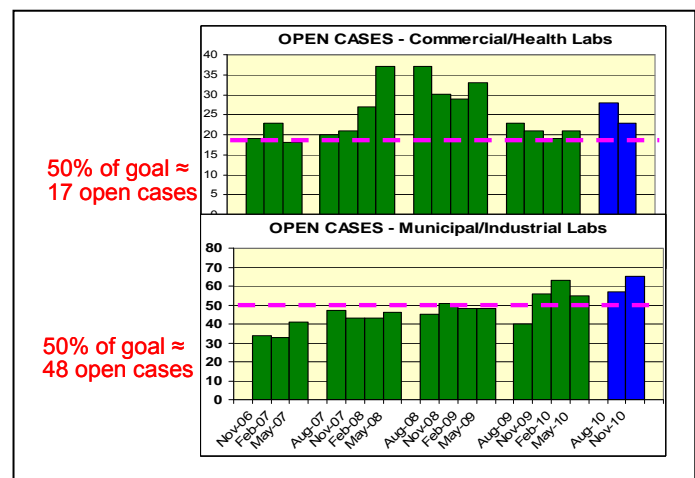
C. Jack Sullivan opened the discussion by noting that it was his understanding that the program goal is for 90% of audit reports to be issued within 30 days of the on-site evaluation. Sullivan went on to state that he was concerned that the program is not performing as well as it should. Sullivan added that the likely causes were either too many labs are being assigned to auditors, or audit staff are not writing reports.

D. Dave Kliber commented that accountability needs to be built into the system. In the private sector, there would be performance reviews, and employees would be warned and severity progress from there. As an advisory council, Kliber indicated that he could not see how we can go on with worsening numbers.

E. Sullivan questioned whether 30 days represents a realistic metric. He noted that when one looks at audits released within 60 days, the percentages improve significantly. Sullivan addressed Kliber's concerns by indicating that the Department also does annual performance reviews for all staff. Sullivan pledged to go back and review staff performance reviews with respect to these concerns. He added that the Department has the ability to implement Personal Improvement Plans (PIP) to get employees back on track. Unlike the private sector, these are union employees and the Department has a system which must be used to work with staff to address performance concerns.

F. Kirsti Sorsa asked if the lagging audit reports are related to the current program vacancy. Sullivan responded that the program workload analysis, which was only recently completed, indicated that the program has the capacity to meet the workload.

G. Randy Thater commented that the data suggest that municipal/industrial lab audit reports are not a problem. The problem seems to be much more significant for commercial/public health lab audit reports. Thater also noted that even in the previous version of NR 149, prior to establishing a turnaround time for audit reports, labs were required to respond to an audit report within 30 days of receipt. If the response is required within 30 days, Thater believes that the auditors should be held to 30 days to write reports. Sullivan responded that he was not aware of the basis for the 30 day timeline, but added that if we expect labs to comply, then we need to comply as well. Rick Mealy commented that the 30 day timeline was put into administrative code because our statutes direct us to consider national standards. The only national lab accreditation program, NELAP, also requires a 30 day timeline for report generation.

H. Paul Junio stated that he was glad to hear that the discussion is not focused on changing the 30 day audit report requirement. He added that there are two commercial labs that have gone a year without receiving a report. Several others are closing in on a year with no report. Junio believes that the further removed one gets from the audit, the more difficult it is to write the report. The quality of the report also declines.

I. Sharon Mertens also commented on the discrepancy in the data between lab types, noting that the problem is more pronounced for large commercial labs. Sullivan commented that for large out-of-state labs, auditors often spend 5 days in the lab; he wonders if it is then reasonable to write a report within 2-3 weeks. Paul Junio noted that in his lab's last NELAP audit, he was provided with a draft audit report before the auditors left. He is surprised labs that have not received audit reports are not asking for them.

J. Paul Harris added that the program should not be re-inventing the wheel. He suggested that we look into how other states, such as Iowa and Minnesota deal with reports. Dave Kliber added that the Midwest Lab Summit is being held in Chicago on December 2-3. Other states and EPA personnel will be present, providing a networking opportunity. Sullivan asked Kliber to provide Kelly Thompson with a link to the information.

K. Sullivan stated that the program will look into the situation and report back in three months. He requested feedback from the Council on the program. Sullivan summarized that what he heard from the discussion is that 30 days is a reasonable requirement, commercial lab audit reports are the focus, and that there is a need to streamline the report generation process. Dave Kliber recommended using a process management approach.

L. Chris Groh offered a couple of comments: (1) with commercials labs, the data do not indicate whether the length of time cases are open is related to deficiencies or something else. (2) Most municipal labs he has worked with respond to their audit report within a week or so. Groh also asked if any consideration had been given to suspending new audit activity for a month to allow staff to catch up. Paul Harris agreed it might be appropriate to take some time to catch up and make changes to the process.

M. Thater commented that the discussion to this point has been focused on reports, but for municipal labs

the issue is more the number of open cases and the length of time since the audit.

N. Dave Kliber stated that what he hears from his constituency is that they do not hear anything (regarding overdue audit reports from LabCert). Sharon Mertens suggested posting a spreadsheet of the backlog on the website and include the date on which the lab response to the audit report was received.

O. Jack Sullivan raised the idea of establishing a subcommittee tasked with putting together what a streamlined report might look like and how to generate it.

P. Paul Junio raised two issues related to audit reports: (1) he noted that a new lab has applied to the program. He performed an internet search on the lab and learned that there was a September 2010 report of men in suits and sidearms entering the lab on suspicion of data fraud. (2) Regarding reports themselves, Junio asked, "*if I request an audit report from a lab, can I obtain a copy of the lab's audit response? I asked for one recently, and all responses could not be found.*"

Q. Sue Hill noted that whenever there is any communication between a lab and the auditor there should be a standard form of communication and mechanism for storage. The question is, "will the next auditor have access to all e-mails and correspondence?"

R. Tom Hungerford asked if there had been any discussion of offering "preliminary" audit reports, perhaps containing the most significant issues identified. This could be something sent via e-mail. Jack Sullivan responded that he wasn't certain that adding a step in the process would be beneficial. Sharon Mertens noted that some auditors leave a draft report after the conclusion of the on-site evaluation. Paul Harris added that Minnesota operates ion this fashion.

IV. Budget Variance Report

	ACTUAL	BUDGET	% of BUDGET
Salary	$ 82,699	$347,639	**23.79%**
Fringe	$ 40,179	$168,918	**23.79%**
Supplies and IT*	$ 5,294	$ 84,100	**6.29%**

* *Does not include IT costs.*

Last Salary Entry: 10/09/2010
Last Supplies Entry: 11/04/2010

A. Tom Hungerford asked if Supplies and IT could be split out. Dave Kliber asked if better detail could be made available for the February meeting. Sullivan commented that perhaps Rick Mealy could be provided access to the data to pull out more information.

V. Variances
None.

VI. Auditor Consistency
A. Dave Kliber opened the discussion by noting that previously, WELA (Wisconsin Environmental Lab Association) had inquired about standards used by auditors for the audit process, and Mealy had provided council members with a link to the program SOP on the LabCert website. Paul Harris commented that while the SOP has been touched upon previously, it needs to be continually revisited. Sue Hill and Dave Kliber suggested that the SOP be reviewed at the next Council meeting.
B. Jack Sullivan asked Council members if they believed auditor consistency to be an issue. Kliber responded that while protocol can become a trap which bogs auditors down, the more critical issue is that one lab gets cited for a particular infraction while another does not. Kliber added that he has advocated for guidelines rather than protocol.
C. Sullivan noted that one thing the program has done is to have all reports reviewed by one individual. Whether that review addresses concerns of inconsistency is a separate issue.
D. Sue Hill commented that consistency needs to go back to the auditors. Some auditors audit from memory, while others come in with very detailed checklists. If auditors conduct audits very differently, there will be inconsistency. Sullivan cautioned that if two people can approach things differently but arrive

at the same conclusion, he doesn't want to stifle professionalism or style. Hill agreed with Sullivan's point but emphasized that reports have to be connected all the way back. Just because the Council advocates using checklists does not imply that the Council expectation is that audits are conducted by simply reading off the checklists.

E. Paul Harris stated that checklists should include lots of places for comments. Auditors need to understand that the checklist is merely a tool. The polarization on the issue (I hate checklists vs. I love checklists) needs to end.

F. Dave Kliber noted that this represents a solid argument that regulatory agencies need to talk to each other. Mealy brought the "State Assessor's Conference call" to the attention of the Council. This is a quarterly opportunity for all state auditors to raise audit issues during an open discussion.

VII. Open Issues

A. Dave Kliber opened the discussion by reviewing the Non-Target Compounds issues, which continues to be a concern for laboratories. Paul Harris noted that drinking water is the biggest area of concern. He questioned why the Department doesn't require routine analysis of EPA Method 525.2 for all target analytes, rather than just a handful of compounds. He added that waivers (from analysis) pose a problem as well.

B. Paul Junio summarized the issue by stating the prior version of NR 149 required labs to report any compound detected. That language was subsequently removed with the updates to NR 149. However, NR 809 still says "report anything detected". From a lab standpoint, what happens then is that a client requests analysis for analyte "X" and the lab reports results for both "X" and "Y".

C. Sullivan asked if there is a case where reporting something which was not requested poses a problem. Junio offered vinyl chloride as an example. Lab "X" has a reporting limit of 5 ppb. Samples have been "no-detect". For some reason the samples get moved to analysis by another lab which offers a lower reporting limit. Now detections for vinyl chloride appear. The client goes back to lab "X", and sure enough, vinyl chloride is present, but below their reporting limit. Sullivan asked if it led to a known environmental problem. He added that where you can win is if you can demonstrate that the issue poses an environmental risk. Short of that, attempts to implement an increased regulatory burden will fail. Sullivan concluded by indicating that Kelly Thompson could check to see if we've had any discussions with the Drinking Water/Groundwater program.

VIII. Other Program & DNR Business

A. NR 149 Rule updates – Kelly Thompson noted that a pink sheet to re-open NR 149 is currently in for legal review. Sullivan reminded the Council that in agency language, a "pink sheet" is a signal to everyone impacted that something is happening.

B. NR 219 Rule updates – Thompson also added that NR 219 is being "pink sheeted" as well based on the recent EPA Federal Register notice regarding changes to approved methods. Rick Mealy offered a brief summary of the Federal Register proposed rule. Mealy noted that barring any extension to the comment period, the program plans to post its comments on the website around the November 22nd deadline.

C. Audit contractor – Thompson indicated that the program is moving forward with securing the services of a contract auditor. This would be a "pay per audit" situation. The plan is to have the contractor perform enough audits so that we wouldn't have to suspend auditing to address other program needs. Sullivan added that the program, is seeking an individual to perform WWTP audits to free up time from other auditors to address the commercial lab backlog. He added that it is reasonable to plan for us having someone in place by the first of the year.

D. Phosphorus Rule – Chris Groh asked what will come out of this new rule: what are the proposed discharge limits? How low will they be? Sullivan asked if those questions had not been answered by the DNR. Groh responded that everyone with whom he speaks has a different answer. Wisconsin Rural Water has tried talking to basin engineers, supervisors, etc., with no firm answers. Sullivan asked Groh to send him an e-mail voicing his concerns and he would work to get answers. Groh offered that a webinar on the rule will be held tomorrow and he hopes the issue will become clearer following that. Sharon Mertens suggested that LabCert help the people making decisions understand the limitations of available methods. Sullivan agreed, and noted that Thompson and Mealy can work on that. Council members agreed to check back on this issue next quarter.

E. <u>Section Chief vacancy</u> – Sullivan indicated that he still lacks approval to fill the position from DNR management, and thus it has not gone on to the Department of Administration (DOA). If the request to fill doesn't get over to DOA by the end of December, we're likely to see a freeze on all hiring.

Kliber asked if the program could function without a chief. Sullivan responded that it would be virtually impossible as the chief provides oversight to three separate programs: Lab Certification, Operator Certification, and Environmental Fees.

Sullivan added that his intent is to have the position posted within a few weeks. He feels that he will announce it internally as he believes there are a lot of good candidates. If he can't fill it from within, it would likely be a failed recruitment and it would take much longer to fill it from outside.

F. <u>Minnesota Certification Situation</u> – Mealy and Sullivan informed the Council of a development arising from the Minnesota Pollution Control Agency (MPCA). Mealy briefed the Council that the MPCA was interested in allowing <u>either</u> Wisconsin DNR or MN Department of Health (MDH) certification to perform compliance testing for MPCA. This would be a change, as historically MPCA has <u>only</u> allowed MDH certification, and might result in a number of Minnesota labs applying for certification. It is largely a cost issue, as the cost of MDH certification is substantially greater than the cost of WDNR certification.

Sullivan indicated that he had been approached by MPCA to provide a number of audits. If MPCA passes this new rule, then we might see a lot of labs applying for certification. Sullivan added that he raised the issue to DNR senior management and, while they had no interest, Sullivan would still like to hear the Council's opinion. Should the program continue discussions with MPCA? He doesn't think that (DNR) Secretary Frank would take any action at this point. Sullivan expressed concern over involvement in this if we can't get our current workload done on time. Sullivan recognizes this would be a source of revenue. And suggested that it might make sense for those facilities that discharge to a system for which we share environmental impact concerns.

Paul Harris commented that this was a perfect situation for a contract auditor. Dave Kliber felt it was further reason to examine our processes, streamline them, and inject accountability. Paul Junio was concerned about how the program would handle an onslaught of applications. Paul Harris commented that there appears to be little communication from the MDH to the MPCA, adding that MPCA is not even invited to MDH meetings. Randy Thater indicated that he did not feel this is consistent with the LabCert program mission. He'd be upset if we're paying fees for audits conducted in Minnesota, particularly in light of the late reports and lengthy list of open cases.

Sullivan discussed inviting members of the MPCA (e.g. Luke Charpentier) to the Council's February 2011 meeting. He added that the state rule is open to interpretation, and we could draw the line at facilities that share a resource of our interest.

IX. Council Member Issues

A. Dave Kliber attended the ACIL annual meeting. There was a joint session dedicated to emergency preparedness. He isn't sure where Wisconsin is on this issue, but the EPA requires ISO certification. The intent is to establish a list of lab capabilities. Jack Sullivan noted that the State Lab of Hygiene is one of six labs nationwide with a Level II accreditation. Kliber indicated that a number of commercial labs have expressed interest in involvement. Sullivan responded that labs should connect with the State Lab of Hygiene as they've taken that role beyond the DNR.

B. Randy Thater briefly discussed another emerging rule, the Thermal Rule. The initial assumption and planning suggested that WWTPs would not be impacted and therefore the wastewater community was blindsided. While it will likely be written out at the next permit, a year of monitoring is required.

X. Next Meeting Date

A. The next Council meeting was tentatively scheduled for Tuesday, February 8, 2011 at the DNR Science Operations Center (2801 Progress Road, Madison).